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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/658,699 | 09/08/2000 | Birgit Oppmann | DX01042X | 3652 |

28008 7590 11/17/2004

DNAX RESEARCH, INC.
LEGAL DEPARTMENT
901 CALIFORNIA AVENUE
PALO ALTO, CA 94304

EXAMINER

VANDERVEGT, FRANCOIS P

| | |
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| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/658,699

Applicant(s)

OPPMANN ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-66 and 69-79 is/are pending in the application.
- 4a) Of the above claim(s) 74-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-66, 69-73 and 79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application claims the benefit of the filing date of provisional applications 60/153,281 and 60/164,616.

Claims 1-62, 67 and 68 have been canceled.

New claims 74-79 have been added.

Claims 63-66, and 69-79 are currently pending.

Election/Restrictions

1. Newly submitted claims 74-78 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: new claims 74-78 are drawn to a method of detecting antibodies to the IL-B30/p40 complex, including the detection of antibodies that are naturally occurring in animals that have not been immunized with the complex or a fusion protein. In contrast, the elected method presently under examination is a method of immunizing animals with the complex or fusion protein to generate antibodies that are the direct result of this manipulation. The method of detection of claims 74-78 is separately classifiable in class 435, subclass 7.1 from the immunization method of claims 63-66, 69-73 and 79 (424/184.1) and requires the search of naturally occurring antibodies that is not required for examination of the invention elected by original presentation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **claims 74-78 withdrawn from consideration** as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly, **claims 63-66, 69-73 and 79 are the subject of examination** in the present Office Action.

2. In view of Applicant's amendment filed August 9, 2004, all previous grounds of rejection are withdrawn. **The following new grounds of rejection have been necessitated by Applicant's amendment.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 63-66, 69-73 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

In base claim 63, the method is drawn to preparing an antibody or fragment thereof, however there are no preparative steps in the method. The method recites "raising an antibody to the IL-B30/p40 complex" and "determining the specificity of the antibody raised in step (a)." The claim does not comprise a step where the "raising" of the antibody occurs. How is the antibody raised? Is it by the immunization of animals to generate the antibodies or is it by screening a phage display library? Antibodies are not simply "raised," they are generated in a specific response to an immunogen. However, the claim has no step regarding the generation of any antibody. This is no connection between the "preparing an antibody" in the preamble of the claim and the conclusion of "confirming that antibody binds." The statements are not linked by any rational, cohesive steps.

Base claim 69 is similarly flawed. The claim is drawn to a "method of an antibody or fragment thereof" [sic] to the IL-B30/p40 complex. However, the claim comprised only a single step of "providing candidate antibodies or fragments that bind to the IL-B30/p4 complex." The claim does not comprise a preparative step whose execution would result in the generation of antibodies specific for the complex or fusion protein.

4. Claims 69-73 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 69 is ambiguous and unclear in the recitation of "method of an antibody or fragment thereof" in the preamble of the claim. The amended preamble fails to indicate what type of method is claimed because an "antibody" and a "fragment thereof" are compounds, not methods.

Conclusion

5. No claim is allowed.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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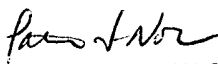
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. 
Patent Examiner
November 10, 2004


PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER

11/10/04